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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/038,342

10/23/2001

Michael Sogard

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,342

Applicant(s)

SOGARD, MICHAEL

Examiner

Mark L. Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/23/01; 7/11/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-37 are pending. Claims 1-32 are withdrawn from consideration. Claims 33-37 are examined.

Election/Restrictions

2. Applicant's election with traverse of Group V, 33-37, in the reply filed on 11/20/2003 is acknowledged. The traversal is on the ground(s) that Groups IV and V cannot be used to practice another and materially different process under the guidelines set forth in MPEP 806.05(e). Applicant argues that the explicit elements of the present claims are substantially similar; that the process and apparatus elements are not materially different, and that both process and apparatus result in the redistribution of DNA, (distinguished from the facts and issues of *Caterpillar Tractor Co. v. Commissioner of Patents & Trademarks* (650 F. Supp. 218, 231 USPQ 590 (E.D. Va. 1986))). Applicant argues that because the redistribution of DNA is used in the process of making an array, the process as claimed in the present claims remains substantially the same. Applicant argues that examining Groups IV and V together will not result in an undue burden on the examiner.

Applicant also traverses the restriction between the process and apparatus of Groups I and III, on similar grounds. Applicant argues that the invention as claimed is not used to practice another and materially different process and does not present an undue burden to the examiner.

This is not found persuasive because the apparatus of Group V can be used to practice another and materially different process such as redistribution of DNA in the

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process of making an array. Also, the container "having" a solution of DNA, can have a solution of protein, as well (the term "having" is considered as open). It is noted that the specification states:

"Target" refers to a nucleic acid molecule or protein that has an affinity for a given probe. Targets may be naturally-occurring or man-made nucleic acid molecules or proteins. Also, they can be employed in their unaltered state or as aggregates with other species. Targets may be attached, covalently or noncovalently, to a binding member, either directly or via a specific binding substance. Targets are sometimes referred to in the art as anti-probes. A "Probe-Target Pair" is formed when two macromolecules have combined through molecular recognition to form a complex.

Specification at para [0033]. The examiner also respectfully submits that the apparatus of Group V also may be used for redistribution of protein, rather than DNA, so that the Inventions of Group IV and Group V are distinct. Furthermore, the method Invention of Group IV, drawn to incubating under thermophoretic conditions, is not of the same scope as the apparatus of Group V, which does not recite a limitation to thermophoretic conditions. Because the inventions are not of the same scope, the search for the Inventions of Groups IV and V will not be coextensive to each other. Therefore, the examiner respectfully submits that examination of the claims of both Groups IV and V would place an undue administrative burden on examination.

Applicant's traversal of the restriction between Groups I and III is not persuasive, because the process Invention of Group I may be practiced by manually heating various sections of the array without the use of temperature control blocks, as recited in the apparatus claims of Group III. Furthermore, the apparatus of Group III may be used to practice another and materially different process that is temperature gradient gel electrophoresis, (temperature gradient gel electrophoresis is taught in the instant

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specification at para [0010]). Therefore, the examiner respectfully submits that examination of the claims of both Groups I and III would place an undue administrative burden on examination.

The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims of Groups IV and V and Groups I and III. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Claims 1-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/20/2003.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 10/23/2001 and 7/11/2003 are considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33, and its dependent claims, recites the language "thermal gradients in the solution which result in the redistribution of DNA" which renders the claim vague and indefinite, because the term "result in" may refer to one of many contributing causes of redistribution, or to some proximate and more direct cause of redistribution.

Claim 34 recites limitations to an inlet port and an outlet port, but does not indicate what component of the apparatus that the inlet port or outlet port connects to, thereby rendering the claim vague and indefinite. For example, it is unclear whether the inlet and outlet ports are connected to the container, or to the temperature control system.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 33-35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ke et al., Nucleic Acids Research, 1996, Vol. 24, No. 4, pp. 707-712.

The claims are drawn to an apparatus comprising a container having a solution of DNA therein; and a temperature control system, wherein said temperature control system creates thermal gradients in the solution which result in the redistribution of DNA.

Ke et al., throughout the publication, and especially at the abstract, p. 702, para 3 -- p. 708, para 4, and Figure 4, teach an apparatus that resembles a conventional vertical gel electrophoresis unit reads on a container with inlet and outlet ports (as in claim 34), optical access to the unit (as in claim 35), and wherein the unit comprises at least some plastic (as in claim 37), wherein the unit generates parallel or perpendicular temperature gradients that are established by aluminum heating plates sandwiching glass plates, between which a solution of DNA is run through an acrylamide gel; and a further comprises a temperature control system that creates thermal gradients in the

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solution which determines the electrophoretic mobility of DNA, resulting in the redistribution of DNA.

7. Claims 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Blumenfeld et al., US 6,733,729.

The claims are drawn to an apparatus comprising a container having a solution of DNA therein; and a temperature control system, wherein said temperature control system creates thermal gradients in the solution which result in the redistribution of DNA.

Blumenfeld et al., US 6,733,729, throughout the patent, and at col. 10, line 66-col. 16, line 22, teach an apparatus comprising a container that is a fluidic cell having a base, a glass slide, liquid and a cover, a slide assembly having two slides with acrylamide gel disposed between the slide, or a silicon DNA chip; at col. 5, line 65-col. 8, line 56, teach a wafer that conducts a thermal gradient, and at col. 7, lines 31-40, a gradient apparatus that includes control circuitry and temperature control system. The temperature control system creates thermal gradients in the wafer that, in turn, creates thermal gradients that are transferred to strata placed on the wafer (specification at col. 5, lines 5-12). The strata may comprise nucleic acid, such as DNA, or DNA chip (specification at col. 13, line 64-col. 14, line 15). Blumenfeld teaches that samples can be placed on the strata having a thermal gradient, in order to assess thermal stability at a variety of temperatures, (col. 12, lines 17-27). The thermal gradient changes the stability of DNA hybridization as function of location on the thermal, and results in DNA

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from certain locations on the gradient washing away, thereby resulting in the redistribution of the DNA into solution (e.g., col. 13, line 64-col. 14, line 15). The reference of Blumenfeld, at col. 11, lines 25-54, teaches embodiments that disclose a microscope slide and coverslip with a small drop (approximately 50 microliters, encompassed by the limitations of claim 36) of water containing DNA (col. 10, line 66-col. 11, line 38); or a DNA chip fluidic containing a glass microscopic slide and liquid film with a volume of approximately 120 microliters, (encompassed by the limitations of claim 36), wherein the base of the fluidic cell is made from lucite, which reads on a container that is plastic, (as in claim 37), and fill holes, for introducing fluid, and which absent evidence to the contrary, may be used for removing fluid, thereby reading on inlet and outlet ports, (as in claim 34). Blumenfeld, at col. 11, line 65-col. 12, line 16, discloses an embodiment comprising an acrylamide gel. Blumenfeld at col. 1, line 66-col. 2, line 17, contemplates detection methods, including microscope systems which, in relation to the aforementioned microscope slide and coverslip, which read on apertures to permit optical access to the container (as in claim 35).

8. Claims 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakao et al., US 6,589,740.

The claims are drawn to an apparatus comprising a container having a solution of DNA therein; and a temperature control system, wherein said temperature control system creates thermal gradients in the solution which result in the redistribution of DNA.

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Nakao et al., throughout the patent, and at col. 4, line 59-col. 5, line 6, teach an apparatus (that reads on the container of the claimed invention) for imposing a thermal gradient on a slab gel containing oligonucleotides, wherein the apparatus contains inlet and outlet ports for hot and cold water flow; at col. 12, lines 18-36, wherein the temperature gradient is a denaturing gradient; at col. 12, line 62-col. 13, line 22, wherein the gradient is generated by temperature control equipment; at col. 3, lines 19-33, and at col. 3, lines 59-10, teach the hybridizing molecule as DNA; at col. 1, line 65-col. 2, line 27 and Fig. 5, teach that denaturing gel electrophoresis (including where the denaturant is a thermal gradient) as resulting in changes in the electrophoretic migration of nucleic acids (which reads on redistribution in solution); and at Fig. 4, for example, show DNA gels, demonstrating optical access to the container, as in claim 35.

Conclusion

9. Claims 33-37 are rejected.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Zhu et al., Biochemistry, 1997, 36, 15326-15335.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

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BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'B. Celsa', written over the printed name and title.